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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,519	09/17/2001	Mitchell Keegan	50179-088	9129

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EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/807,519

Applicant(s)

KEEGAN ET AL.

Examiner

Maria B Marvich, PhD

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 October 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 1-3, 6 and 8-13

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☒ Other: See Continuation Sheet


GERRY LEFFERS
PRIMARY EXAMINER

Continuation of 3. Applicant's reply has overcome the following rejection(s): Had the amendments been entered, applicants response would have overcome the rejections under 35 USC 103(a) as claim 1 has been amended to incorporate limitations from claim 3 that have previously been found allowable in regards to prior art.

Continuation of 5. does NOT place the application in condition for allowance because: The amendments have not been entered as they have failed to meet the requirements of 37 CFR 1.121 as amended on June 30, 2003 see attached Notice of Non-Compliant Amendment. The communications filed on 10/8/04, 10/19/04 and 10/20/04 included Non-Compliant Amendments. Future proposed changes should be made relative to the claims filed 2/13/04 due to the non-entry of the After-Final Amendments.

Specifically, the communication filed on 10/8/04 is not fully responsive to the Office communication mailed on 5/5/04. Claim 1 contains insertions (a mature) and deletions (mature) that have not been indicated as added or deleted by underlining or strike-through.

The communication filed 10/19/04 is not fully responsive to the Office communication mailed 5/5/04. Claim 1 contains insertions (a) (, wherein the insulin secretory signal...) and deletions (an), (a mature) that have not been indicated as added or deleted by underlining or strike-through. As well, text is indicated as being deleted (mature) that is not part of the text.

The communication filed 10/20/04 is not fully responsive to the Office communication mailed 5/5/04. Claim 1 contains insertions (, wherein the insulin secretory signal...) that have not been indicated as added by underlining. As well, text is indicated as being deleted (a) that is not part of the text and added (an), (a mature) that is already part of the text.

Furthermore, according to the requirements of 37 CFR 1.121 "previously amended" is not proper terminology but "previously presented" is appropriate.

Continuation of 10. Other: Applicants traverse the rejection under 35 USC 112, first paragraph, in the amendment filed 10/1/04. Applicants argue that although the term "mature somatotropin" does not appear in the specification, the skilled artisan would recognize the polypeptide in figure 1 and 2 as the nucleotide and amino acid sequence respectively of mature somatotropin as evidenced by O'Mahoney et al. O' Mahoney et al teach that porcine somatotropin is 216 amino acids long and mature somatotropin is 190 amino acids long and therefore, the sequence in figure 2 represents "mature somatotropin".

Applicants invention is drawn to fusion of an insulin secretory signal to the coding sequence of somatotropin. In amending the claims to recite that the somatotropin is "mature somatotropin", applicants rely on the disclosure of the porcine somatotropin sequence in figure 2. Applicants do not have literal support in the originally disclosed specification for use of the term "mature" but instead rely on the inherency of "mature somatotropin" to figure 2. Figure 2 is described as "Insulin secretory signal- pST peptide sequence". While the skilled artisan will recognize that the sequence is that of "mature" porcine somatotropin, the skilled artisan would not recognize that this sequence indicates that the invention is drawn to the class of somatotropins that are "mature". Therefore, the inclusion of "mature somatotropin" lacks written description and amounts to impermissible new matter.